UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES ONLY TO: **WAVE ONE PROLIFT, PROLIFT+M AND PROSIMA CASES LISTED ON EXHIBIT A**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF RUSSELL DUNN, PH.D., P.E.[1]

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") submit this reply memorandum in support of their motion [Dkt. 2058] to exclude the opinions and testimony of Russell Dunn, Ph.D., P.E., Plaintiffs' chemical engineering expert.

I. ARGUMENT

A. *Huskey* Is Not Controlling

Plaintiffs make much ado over the fact that this Court denied Ethicon's *Daubert* challenge to Dr. Dunn in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 710-711 (S.D. W. Va. 2014). That decision was entered relatively early in this litigation. Much has been learned about Dr. Dunn and his lack of qualifications since that decision. Ethicon's current motion to exclude Dr. Dunn is vastly different from its motion in *Huskey*.

Plaintiffs say that this Court again allowed Dr. Dunn as an expert in *Mathison v. Boston Sci. Corp.*, No. 2:13-cv-05851, 2015 U.S. Dist. LEXIS 59047 (S.D. W. Va. May 6, 2015). Pltfs.'

[1] The specific cases to which this memorandum relates are listed in Ex. A. Unless otherwise noted, all exhibits referenced herein are attached to Ethicon's Motion.

Resp. [Dkt. 2173] at 2 n. 4. However, that is not true. *Mathison* is actually one of a number of post-*Huskey* cases in which this Court has uniformly held that Dr. Dunn is not qualified to express the opinions for which Plaintiffs offer him as an expert. *See Mathison*, 2015 U.S. Dist. LEXIS 59047, at *65-69; *see also Stewart v. Boston Sci. Corp.*, 2016 U.S. Dist. LEXIS 60812, at *26-27 (S.D. W. Va. May 9, 2016); *Carroll v. Boston Sci. Corp.*, 2016 U.S. Dist. LEXIS 60335, at *26-27 (S.D. W. Va. May 6, 2016); *Bethune v. Boston Sci. Corp.*, 2016 U.S. Dist. LEXIS 59641, at *26-27 (S.D. W. Va. May 5, 2016); *Trevino v. Boston Sci. Corp.*, 2016 U.S. Dist. LEXIS 56538, at *65-68 (S.D. W. Va. Apr. 28, 2016); *Wilkerson v. Boston Sci. Corp.*, 2015 U.S. Dist. LEXIS 58671, at *52-56 (S.D. W. Va. May 5, 2015); *Frankum v. Boston Sci. Corp.*, 2015 U.S. Dist. LEXIS 57251, at *47-51 (S.D. W. Va. May 1, 2015); *Carlson v. Boston Sci. Corp.*, 2015 U.S. Dist. LEXIS 55282, at *50-54 (S.D. W. Va. Apr. 28, 2015); *Winebarger v. Boston Sci. Corp.*, 2015 U.S. Dist. LEXIS 53892, at *69-73 (S.D. W. Va. Apr. 24, 2015).

B. Dr. Dunn's "Polymer Failure Opinions" Are Challenged

Plaintiffs say that Ethicon has not challenged Dr. Dunn's "Polymer Failure Opinions." Pltfs.' Resp. [Dkt. 2173] at 2 & 8. That is not true. Plaintiffs attempt to blur the distinction between "Polymer" in general and Prolene. As explained in Ethicon's Memorandum, the essence of Dr. Dunn's "Polymer Failure Opinions" is that "Ethicon's Prolene undergoes oxidative degradation in the body, that the oxidative degradation is a hazard that cannot be eliminated . . . ." *See generally* Ex. B, Dunn Report. Plaintiffs' own response admits that they seek to have Dr. Dunn "conclude that Prolene degrades in the body" and further opine that Prolene should not be used as a pelvic organ prolapse device because of this alleged degradation. Pltfs.' Resp. [Dkt. 2173] at 9-10. Ethicon's Memorandum specifically challenges all of Dr. Dunn's Prolene failure opinions.

A large portion of the "Polymer Failure Opinions" section in Dr. Dunn's report concerns unstabilized (or generic) polypropylene, not Prolene. Plaintiffs say that "Dr. Dunn's opinions on the inherent nature of polypropylene to oxidize . . . are central to the jury understanding . . . ." Pltfs.' Resp. [Dkt. 2173] at 7. It is true that Ethicon does not challenge Dr. Dunn's opinion that unstabilized polypropylene can degrade. Ethicon's Memorandum explained that its objection to this opinion is simply that it is not relevant, is not helpful to the jury, and in fact would tend to confuse the jury given that there is a very significant difference between unstabilized polypropylene and Prolene.

C. Ethicon Does Challenge Dr. Dunn's Opinions That Ethicon's FMEAs "Are Not Being Used Properly"

Plaintiffs say that Dr. Dunn's opinions that Ethicon's FMEAs "for the products in question are not being utilized correctly . . . are not challenged." Pltfs.' Resp. [Dkt. 2173] at 4. They also say that Ethicon's Motion does not dispute Dr. Dunn's opinion that "Ethicon is not following the requirements of the FMEA risk analysis." Pltfs.' Resp. [Dkt. 2173] at 5. These statements are incredibly far from a plain reading of Ethicon's Memorandum. A fundamental premise of Ethicon's Motion is that Dr. Dunn's expertise has nothing to do with procedures for performing FMEAs *for medical devices under ISO 14971*, or any other accepted medical industry standard for that matter. *See* Defs.' Mem. [Dkt. 2064] at 4-8.

Plaintiffs also say that Ethicon has only challenged Dr. Dunn's expertise to testify as to "*how* Prolene oxidizes in the body." Pltfs. Resp. [Dkt. 2173] at 4 & 9 (emphasis added). Again, this statement is not at all true. For examples, Ethicon has specifically challenged Dr. Dunn's expertise to opine that Prolene does degrade (regardless of "how") in the body, that further testing of Prolene is needed, that Prolene should not be used in the body, that the use of Prolene in the body is a hazard – the list goes on. *See* Defs.' Mem. [Dkt. 2064] at 4-8.

D. "Oxidation of Prolene" Need Not Be Listed In An FMEA

Plaintiffs' Response confirms Dr. Dunn's insistence that unless "oxidation" is expressly listed and analyzed within a separate FMEA for each product, then it is conclusive that Ethicon has never considered oxidation as a potential failure mode for that product. Pltfs.' Resp. [Dkt. 2173] at 6-7. This position glaringly reveals Dr. Dunn's lack of expertise in FMEAs for medical devices under ISO 14971.

As explained in Ethicon's Memorandum, ISO 14971 specifically provides that when prior analyses of a potential risk, such as oxidation, are available for a component of a medical device, the manufacturer need not repeat the analysis of that risk, but rather "can and should" rely on the prior analysis. Ex. H, ISO 14971:2007 at 19. Moreover, ISO 14971 expressly provides that risk analysis of degradation be conducted in accordance with ISO 10993. *Id*. at 76-77. Dr. Dunn ignores these important standards. Plaintiffs confirm Dr. Dunn's position stating "[t]here is no need for Dr. Dunn to return to the ISO standards to form his opinions because those standards specifically state that the FMEA contains everything that a medical device risk analysis needs." Pltfs.' Resp. [Dkt. 2173] at 11. Plaintiffs failed to give, and indeed could not give, any citation in ISO 14971 or any other standard to support this incorrect proposition. Instead of following ISO 14971, Plaintiffs candidly acknowledge that Dr. Dunn blinds himself to any analysis that is not repeated every time a new FMEA is created for a modification to a device even though the essential component, Prolene, has not changed and has previously been evaluated for oxidation. Pltfs.' Resp. [Dkt. 2173] at 7.

Dr. Dunn's opinions are not reliable because he refused to consider the various biocompatibility risk assessments performed on the Prolene mesh pursuant to ISO 10993, as discussed in Ethicon's Memorandum.

E. Dr. Dunn's Lack Of Experience With ISO 10993 Renders Him Unqualified

Plaintiffs say that "[t]he only question put forth is to [Dr. Dunn's] qualifications in regards to *performing the tests* required by the FMEA and, evidently ISO 10993." Pltfs.' Resp. [Dkt. 2173] at 10. That is not a true statement. Ethicon is not so much concerned with whether Dr. Dunn has expertise in carrying out the performance of testing under ISO 10993. The real concern and challenge to Dr. Dunn relevant to ISO 10993 is his opinion that Ethicon's risk analysis of Prolene should have included more testing for oxidative degradation. He had no idea that ISO 10993 includes *the* standard for determining whether more testing is needed. Dr. Dunn cannot possibly be considered an expert to opine that Ethicon should have conducted further testing of Prolene for oxidative degradation when he does not even know there is a formal standard that governs the determination as to whether additional testing is needed.

Plaintiffs' Response expressly admits that Dr. Dunn has no expertise at all regarding biocompatibility. Pltfs.' Resp. [Dkt. 2173] at 12. Ethicon agrees. As explained in Ethicon's Memorandum, the point is that both Dr. Dunn and Plaintiffs fail to understand that under ISO 10993 "biocompatibility" analysis expressly includes degradation. Since Dr. Dunn is not qualified to express opinions concerning the subject of biocompatibility, he cannot possibly be qualified to opine to the jury whether Ethicon properly performed biocompatibility analysis which included all forms of degradation.

F. Dr. Dunn Does Not Understand Ethicon's Internal Standards

Dr. Dunn and Plaintiffs say that Ethicon's internal standards require the use of an FMEA format for risk analysis. However, the use of an FMEA format did not become the required standard for risk analysis within Ethicon until 2005. *See* Ex. FF, PR 602-003 Version 6; Ex. GG,

Revision History for PR 602-003.[2] Prior to 2005, Ethicon's primary risk analysis tool was the "Device Design Safety Assessment" or "DDSA." *Id.* These DDSAs expressly stated that Ethicon had considered the chemical nature and biodegradation of Prolene under EN 30993 (this is another designation for ISO 10993) and determined that no further analysis was needed. *See, e.g.*, Ex. Q, 2002 DDSA for Gynemesh PS at ETH.MESH.00220305. Later the Prolift DDSA expressly referred back to the Gynemesh PS DDSA because the material was not changed. Ex. O, 2005 Prolift DDSA at ETH.MESH.06700947. When Ethicon began following the FMEA format, its standards continued to expressly provide for reliance on prior risk analyses for components of devices that had been previously analyzed – as provided in ISO 14971. Ex. HH, PR 602-003 Version 7 at ETH.MESH.10619662. Thus, for example, the Prosima FMEA conducted in 2007 expressly referred the reader back to the Gynemesh PS DDSA. Ex. P at pdf pages 2 & 15.

Dr. Dunn's blinders obstinately led him to conclude that Ethicon had never considered oxidation simply because he did not see the word "oxidation" in the Prosima FMEA instead of the reference to a prior assessment in which it had been considered. In a nutshell, Dr. Dunn improperly opines that form should control substance and that only his form is acceptable. This type of opinion is not reliable.

G. Quality Systems Standards Do Exist

As explained in Ethicon's Memorandum, Dr. Dunn opines that Ethicon's quality systems are deficient, but he was totally unaware of the existence of any standards by which to evaluate Ethicon's quality systems. Now Plaintiffs have doubled down telling this Court that there are no written quality systems standards. Pltfs.' Resp. [Dkt. 2173] at 11. Plaintiffs say that 21 CFR Part

[2] Exhibits FF, GG, HH, II and JJ are attached hereto.

820 only gives general requirements for quality systems. *Id*. at 11-12. However, they ignore the FDA's guidance documents for quality systems. They also ignore the Global Harmonization Task Force guidance for medical device quality systems. Ex. II, Global Harmonization Task Force, Guidance on Quality Systems for the Design and Manufacture of Medical Devices. Perhaps most importantly, Plaintiffs are contradicting the express opinion of their own expert, Anne Wilson, who opines that ISO 13485 has been the standard for medical device quality systems for many years. Ex. JJ, Wilson TVT-R Report at 2 & 5.

II. CONCLUSION

For the reasons set forth above, the Court should exclude the opinions and testimony of Dr. Dunn.

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CERTIFICATE OF SERVICE

I, William M. Gage, certify that on May 16, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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